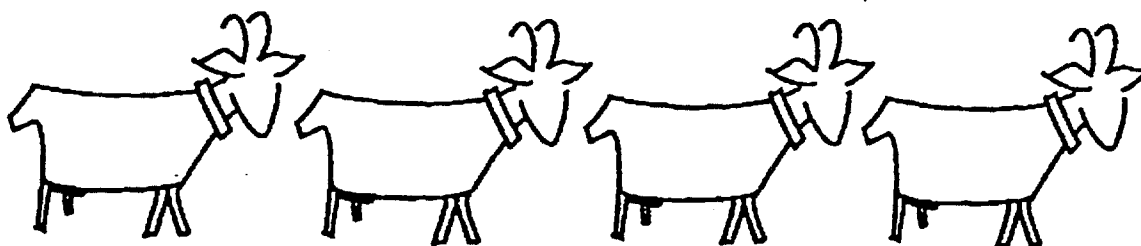


Technical Report

An Economic Analysis of the Production of Contagious Caprine Pleuropneumonia CCPP Vaccine



Willy Njoroge¹

Corinne Valdivia

Jane Wachira

Adiel Nkonge Mbabu

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University of Missouri-Columbia

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¹The authors are Research Associate Kenya Small Ruminant Collaborative Research Support Program (SR-CRSP), Principal Investigator SR-CRSP, Kenyan Veterinary Vaccine Production Institute, and leader Socioeconomics Division Kenyan Agricultural Research Institute and Resident Scientist Social Sciences SR-CRSP, respectively. Any inquiries please address to Valdivia Department of Agricultural Economics, Social Science Unit, University of Missouri-Columbia, 200 Mumford Hall, Columbia, MO 65211, USA.

Willy Njoroge is Research Associate with the SR-CRSP.

Corinne Valdivia is Principal Investigator in Social Sciences.

Dr. Jane Wachira is Collaborating Scientist and Production Manager Kenya Veterinary Vaccine Production Institute.

Dr. A. N. Mbabu is Resident Scientist SR-CRSP and Leader, Socioeconomics Division KARI.

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Introduction

Contagious Caprine Pleuro pneumonia (CCPP) is a disease of major economic importance and imposes a significant constraint upon goat production, resulting from high mortality and morbidity rates. The F38 Mycoplasma strain has been demonstrated to be cause of this disease in Kenya (MacOwan and Minnete 1976) and Sudan (Harbi et al 1981). It has been reported as the most serious infectious disease of goats in Kenya (Rurangirwa and McGuire 1991).

Research by the Kenya Agricultural Research Institute (KARI) and the Small Ruminant Collaborative Research Support Program (SR-CRSP) scientists contributed to the development of a vaccine against CCPP. This vaccine, created during the 1980's, and available in the market in liquid form since 1987 (Lipner and Brown 1995) was improved through an additional production stage, the process of freeze drying (lyophilized form). This process increases the shelf-life of the vaccine and eliminates that need cold storage chains (the liquid form requires storage at 4°C), which are expensive to maintain, especially in areas where CCPP is prevalent. The CCPP vaccine (Caprivax, its commercial name at the Kenya Veterinary Vaccine Production Institute KEVEVAPI) is produced at the production unit Muguga, together with two other vaccines, namely, Contagious Bovine Pleuropneumonia (CBPP) vaccine (Contavax) and the Rinderpest vaccine (Rinderavax).

KEVEVAPI is the only institution in Kenya with the mandate for Caprivax production and fourteen other vaccines. Apart from Muguga production unit, the two other centers where KEVEVAPI produces vaccines are Kabete and Embakasi.

Information obtained from KEVEVAPI and The Veterinary Field Services Office indicate that the demand for Caprivax is low. This viewpoint appears to be corroborated by the low production and sale figures observed in the past. For instance, in the period 1992-1995, production and sales figures have never reached 200,000 doses per year. This contrasts sharply with the national goat population which stands at about 15,000,000.

This means that use and adoption of Caprivax is low. There is need to identify the factors that contribute to this low use and adoption, to inform decision makers both in the production and distribution processes of the constraints and possibilities for disease prevention through vaccine use. What are constraints at the users end, and the constraints

at the production end? The SR-CRSP Social Science research is carrying out research to identify these constraints to the use and adoption of the vaccine. This study investigates the economic efficiency, and institutional constraints and opportunities for the production of Caprivax.

Objectives

The purpose of this research is to study the production and sale of Caprivax by KEVEVAPI for the past five years. The question of whether there exists competition for use of machinery between Caprivax production and the production of other vaccines has been raised by Lipner and Brown (1995) and Mbabu and Nolan (1993). This study addresses the issue of competition and how it may impact on Caprivax production. The study also estimates the cost of production for the both the liquid and the lyophilized forms of Caprivax. Such estimates are important in appraising the economic viability of the production process.

The specific objectives of this study:

- a) to estimate and compare the production costs of both types of CCPP vaccines, liquid vs. Lyophilized using Caprivax as the formula for cost estimation,
- b) to establish whether there is competition for machinery between Caprivax and the two other vaccines that are produced at the Muguga production unit, namely Rindervax and Contavax,
- c) to identify the buyers of Caprivax at KEVEVAPI from 1991 to 1995.

Production of Caprivax

Production of Caprivax involves culturing Mycoplasma F38 in broth media and it takes up to 45 days to produce one batch. There is a protocol for preparing the broth

media and another one for the production process. Materials used in blending the media are all purchased and constitute the largest proportion of variable costs in Caprivax production. Mature Mycoplasma F38 are inactivated using saponin to reduce its pathogenicity and the inactivated form is then packaged and sold as Caprivax. Based on current capacity (plant and equipment) 60 litres of materials can be processed in one batch.

Production Costs

An estimation of costs of production of the Caprivax was carried out using data for the period 1992-1995 (Appendices). Variable inputs used in vaccine production were identified by the KEVEVAPI staff. Price data was also gathered from KEVEVAPI. As expected, fixed costs were more difficult to estimate. Items that were identified as constituting fixed costs are housing of the factory where production takes place, permanent labour and the durable equipment employed in Caprivax production. Labor was valued at its current market value. Capital recovery cost (CRC), the annual payment that will repay the cost of a fixed input over the useful life of the input and will provide an economic rate of return on the investment, was computed to estimate fixed cost. Capital recovery cost estimates both the depreciation and the opportunity costs of the investment. The relevant CRC formula (Pearson and Monke1982) is:

$$R = \frac{Z(1+i)^ni}{(1+i)^n-1}$$

where:

- R = capital recovery cost,
- Z = initial outlay on an investment,
- n = useful life of the investment,
- I = opportunity cost of the investment estimated to be equal to the market rate of interest.

A spreadsheet was used to develop the calculations and analyze the data, as well as undertake sensitivity analysis.

Since production levels varied from year to year, two approaches were used to estimate unit production cost for the Caprivax. One approach was to estimate this component year by year, to determine variations year to year to analyze productivity and changes in levels of production. The second approach was to average production data for the period 1992-1995, and use this average, to compute the expected average production cost for the vaccine for period. The latter approach allows us to judge how year to year variations have deviated from the mean. Table 1 summarizes the results of the computation.

Table 1: Estimation of average cost of production for Caprivax

Year	Total batches	Effective batches		Doses produced	Average Yld/batch	Cost/unit (liquid)	Cost/unit (freeze)
		Total	%				
1992	17	9	53%	66,100	3889	11.60	16.20
1993	31	30	97%	180,450	5821	5.50	8.34
1994	43	25	58%	171,500	3989	7.21	10.20
1995	22	9	41%	67,800	3082	11.83	17.30
Average	29	19	66%	121,463	4300	7.59	11.16

Developed with data gathered from KEVEVAPI during 1996.

Table 1 indicates that on average, it costs about Ksh 7.60 to produce one dose of the liquid form of the Caprivax. It would cost about Ksh 11.20/dose to produce the freeze dried one. At the average yield of 4300 doses per batch, it is estimated that one dose of the liquid Caprivax would have to be sold at about Ksh 4.80/dose to cover the variable costs alone. Therefore, the current price of Ksh 4.00/dose does not even cover the variable

cost of production. In economic terms, it means that the current production process is not viable and that production of the vaccine has only been possible because of cross-subsidization by the other more profitable production lines (that is Rindervax and Contavax). However, in an improved production process where higher yields/batch are possible, unit production cost would decline and hence give economic viability to Caprivax production. This phenomenon will be pursued further in the sensitivity analysis section.

Another observation that is apparent from the table is that there is a very high rate of loss occasioned by contamination of the broth media. When other microorganisms (other than Mycoplasma F38) grow in the broth media, the media is said to be contaminated and is therefore discarded. In economic terms, the cost of the elements that are used in the preparation of the broth medium constitutes the most important component of the variable costs in Caprivax production. Therefore, the loss of the medium through contamination represents a major cost in vaccine production. Table shows that on the average, 34% of the runs will fail because the broth medium has been contaminated.

Another shortcoming in the production process can be discerned by glancing at the production statistics shown in the appendix. According to the information gathered from KEVEVAPI, one batch can yield up to 20,000 doses. However, the estimated average yield using the 1992-1995 data is 4,300 doses per batch, which is only 22% of the possible maximum yield. And there is great variability in yield between batches. To demonstrate this variability, standard deviation was calculated again using 1992-1995 production data. The figure obtained from the calculation is 4,107, which indicates the high degree of variability. This yield variability and the regular loss of broth medium through contamination are veritable pointers to weaknesses in the current production process.

Sensitivity Analysis

In Table 1, we calculated unit costs of production for Caprivax using actual production data for the period 1992-1995. It has already been observed that the current yield levels are much lower than the potential yield level and that this problem is exacerbated by the recurrent loss of the culture through contamination. This section of sensitivity analysis investigates the effect on the unit cost of production of an improved

production process that would increase yield and minimize the frequency of culture media contamination.

Table 2: Sensitivity analysis with different yield levels.

Year	Total batches	Yield/batch	Cost/unit (liquid)	Cost/unit (freeze)
1992	17	1 ^a =3888 2 ^b =7000 3 ^c =10000 4 ^d =12000	11.60 5.87 4.11 3.42	16.20 9.24 7.07 6.11
1993	31	1 ^a =5821 2 ^b =7000 3 ^c =10000 4 ^d =12000	5.50 4.56 3.19 2.60	8.34 7.16 5.40 4.72
1994	43	1 ^a =3988 2 ^b =7000 3 ^c =10000 4 ^d =12000	7.21 4.11 2.88 2.40	10.20 6.35 4.83 4.25
1995	22	1 ^a =3082 2 ^b =7000 3 ^c =10000 4 ^d =12000	11.83 5.21 3.65 3.04	17.30 8.34 6.23 5.41
Aggregate	113	1 ^a =4300 2 ^b =7000 3 ^c =10000 4 ^d =12000	5.53 3.40 2.38 1.98	11.34 5.06 3.93 3.49

Key: a is the actual yield/batch obtained,

b, c, d are three higher levels of yield per batch, sensitivity analysis.

The result of sensitivity analysis indicate that an increase in yield will result in a dramatic decrease in unit cost of production. This can be clearly seen from column four of Table 2 above. This observation is significant to policy makers at KEVEVAPI because an increase in productivity resulting from increased yields and a reduction in broth media contamination is a real technical possibility. Another important result from sensitivity analysis is that mass production of the vaccine rather than limited production is preferable. Mass production brings about production efficiency by ensuring that existing capacity(plant and equipment) are utilized fully.

Competition for Machinery with Contavax and Rindervax

Information obtained from KEVEVAPI reveal that at the current levels of production, there is no competition for plant and equipment between Caprivax production and the production of the other two vaccines that are produced at Muguga. This refutes earlier observations by other researchers (Lipner and Brown, 1992), that competition for machinery and equipment between Caprivax, Contavax and Rindervax vaccines is a constraining factor in Caprivax production. Indeed, the three vaccines are all produced in separate (but adjacent) plants using separate equipment and labor. This precludes the possibility of competition. In the near future however, KEVEVAPI will start producing the freeze dried form of Caprivax and the question that arises is whether the only freeze drier at Muguga will be adequate for the three vaccines. To answer that question, an analysis was carried out using data obtained from the production department of KEVEVAPI. The analysis investigated the number of days that would be available for freeze drying Caprivax and hence the number of batches of Caprivax that could be freeze dried given the production levels of the other two vaccines that prevailed during the period 1992-1995. The results from this analysis are summarized in the Table below.

Table 3: Analysis of competition for the freeze drier

YEAR	Rindervax		Contavax		Caprivax		
	Batches ¹	Days ²	Batches ¹	Days ²	Available Days ³	Possible batches ⁴	Actual Batches ⁵
1992	24	48	7	28	289	72	9
1993	25	50	17	68	247	61	30
1994	15	30	36	144	191	47	25
1995	18	36	28	112	217	54	9

Notes:

- ¹ Batches of the vaccine freeze dried in that year,
- ² Number of days spent freeze drying the vaccine that year,
- ³ Number of days available for freeze drying Caprivax in that year,
- ⁴ Total number of batches of Caprivax that could be freeze dried given available days for that activity,

⁵ Effective batches of Caprivax produced in that year.

Other information not presented in Table 3 which is important in the interpretation of the analysis is that it takes two days to freeze dry a batch of Rindervax, four days to freeze dry Contavax and four days to freeze dry Caprivax. This analysis confirms KEVEVAPI's judgment that the freeze drier would be adequate even in the event of inception of production of the freeze dried Caprivax. The analysis therefore demonstrates that in the production of Caprivax, competition for equipment has not been a constraining factor given past demand trends for the other vaccines, and it is not likely to be, even when the production of the freeze dried form commences, if planning takes place.

Buyers of Caprivax

Table 4 summarizes Caprivax sales data for the period 1991-1995 by identifying six categories of buyers and quantities of the vaccine purchased each year.

Table 4: Buyers of Caprivax between 1991 and 1995 from KEVEVAPI

Year	Govt.	Private	NGO	Export	Research	Parastatal	TOTAL
1991	127500	1009	0	0	0	0	128500
1992	44400	17400	46400	10000	4600	200	122000
1993	150150	41950	0	0	3300	2000	160400
1994	80000	68600	3300	0	2000	0	153900
1995	22850	39250	600	0	1700	0	64400

Source: KEVEVAPI Sales records.

Table 4 shows the Government as the main buyer of the Caprivax. On average, the Government purchases more than 50% of the annual sale of the Caprivax. Before 1995, the Government would pay all the cost of the sale and delivery of the vaccine. However, with the advent of cost recovery policy, farmers are required to pay for the vaccine at its factory price. Therefore, the Government has no obligation to buy the vaccine for farmers.

The implication here is that a major buyer is quitting the market and this may easily translate to a reduction in the vaccine purchases by more than a half. The export market for Caprivax has been very thin and erratic as shown in Table 4. However, the potential for the expansion of this market exists judging from the numerous enquiries made by foreign groups in 1996. Other important buyers are the non governmental organizations (NGOs) and private individuals. With the Government opting out of the market, the levels of future sales will depend on the extent to which purchases by private individuals and NGOs will grow, as trends are showing in Table 4, where the private sector participation has grown in forty times between 1991 and 1995. Non governmental organizations are also participating actively as from personal communications in 1996, vaccines have been requested, and KEVEVAPI has had difficulties in meeting requests result from CCPP outbreaks. This underlines the importance of understanding demand patterns in this new economic environment, and the increased importance of lyophilized vaccines, because these can be stored for a longer period.

Conclusions and Recommendations

Under the current production conditions, the present market price of Caprivax cannot even cover the variable costs of production. Therefore, the continued production of Caprivax by KEVEVAPI is made possible by subsidization. Indeed, according to Brown (personal communications), production of Caprivax is not economical and it is made possible only by the 'support' it gets from other vaccines. Two factors have been identified as contributing to the high cost of Caprivax production. These are the recurrent loss of the culture media because of contamination and the large overhead costs in Caprivax production. Result of sensitivity analysis demonstrated that average cost of production will decrease dramatically with increased yields and a reduction in the frequency of loss of broth media through contamination. Any future effort to improve production efficiency of Caprivax production must therefore seek to increase yields and prevent contamination.

The two possible reasons for the recurrent contamination of the culture are: 1) human error in handling equipment and the broth media, and 2) a deficient production process. We hypothesize that since this problem has persisted for a long time, there has been enough opportunity to correct for human error (e.g. through training and/or shifting of personnel). Hence, we postulate that a deficiencies in the production process are the central problem. We therefore recommend a process innovation in Caprivax production that would not only curtail contamination but also increase overall yields/batch. At the initial stages of Caprivax production for instance, KEVEVAPI was using a Lister machine, which is a cream separator, to separate the antigens from the media. Later however, it acquired a centrifuge to replace the Lister machine. The centrifuge was found to be much faster and to reduce incidence of contamination. Similar innovations in equipment and process are required to eradicate contamination. To increase yields, we recommend that a certified seed stock of *Mycoplasma* F38 be available to KEVEVAPI at all times.

It is also concluded that KEVEVAPI faces a declining sale of the Caprivax with the exit of the Government from the buyers list. The government has been the main buyer of the vaccine, taking more than a half of KEVEVAPI's sales. This scenario is bound to change because of the emergent cost recovery policy that places the responsibility for paying for

the vaccines on farmers rather than the Government. In future, sale volumes for Caprivax will depend on activity of NGOs and that of private individuals.

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Appendix: Annual Production Figures of Caprivax at KEVEVAPI 1992-1996

ANNUAL PRODUCTION FIGURES FOR VACCINES									
CAPRIVAX									
BATCH NO	YEAR 1992	BATCH NO	YEAR 1993	BATCH NO	YEAR 1994	BATCH NO	YEAR 1995	BATCH NO	YEAR 1996
160	4200								
161	5500	177	3200	2	12000	2	2950	1	7500
164	7000	178	1400	3	1000	3	7200	2	4200
165	4200	179	1200	4	2800	4	5700	3	9300
166	7000	180	3300	6	12000	6	5100	4	4550
173	4800	181	5000	7	5200	13	14400	5	9000
174	5200	182	4400	12	6400	16	4250	6	13500
175	17000	183	4600	13	6200	20	4200	7	11200
176	11200	184	5700	14	6400	21	9600	8	8900
TOTAL	66,100	185	5050	16	6000	22	14400	TOTAL	68150
		186	9250	11	4500	TOTAL	67,800		
		187	7550	15	6200				
		188	3500	17	10600				
		189	2550	22	9000				
		190	5250	19	12000				
		191	5700	20	6000				
		192	5600	21	10600				
		193	14500	29	5400				
		194	5800	30	4200				
		195	5600	31	4200				
		196	7200	33	8400				
		197	9600	34	11700				
		198	7800	35	4800				
		199	6400	36	6600				
		200	8400	40	4500				
		201	6300	43	4800				
		203	5200	TOTAL	171,500				
		204	5400						
		205	9200						
		206	8600						
		207	7200						
		TOTAL	180,450						

Source: KEVEVAPI Production Records.